

See Appendix 1 for the marked-up copy of the claims. The terms bracketed were cancelled from the claims and the term underlined was added to the claim.

### REMARKS

Applicants respectfully request reconsideration in view of the amendments and following remarks. The applicants have amended claims 16, 20 and 26 as suggested by the Examiner in order to overcome the 35 U.S.C. § 112, second paragraph, rejections.

Claims 16 through 33 were rejected under 35 U.S.C. § 112, second paragraph. Claims 16 through 22, 27, 28, 31 and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lo et al.* U.S. Patent No. 6,358,520 (hereinafter referred to as "Lo") in view of Hasslin U.S. Patent No. 5,674,514 (hereinafter referred to as "Hasslin"). Claims 23 through 26, 29, 30 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Masters U.S. Patent No. 6,342,250 (hereinafter referred to as "Masters") and *Eppele et al.* U.S. Patent No. 5,376,725 (hereinafter referred to as "Eppele"). The applicants respectfully traverse these rejections.

#### Section 112 Rejection

Claims 16 through 33 were rejected under 35 U.S.C. § 112, second paragraph. The applicants have amended the claims as suggested by the Examiner and believe that the claims as amended are in compliance with 35 U.S.C. § 112, second paragraph. For the above reasons, this rejection should be withdrawn.

#### Section 103 Rejections

Claims 16 through 22, 27, 28, 31 and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lo* in view of *Hasslin*. Claims 23 through 26, 29, 30 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Masters* and *Eppele*.

The applicants believe that *Lo* is the closest prior art. *Lo* discloses a matrix comprising a

water-insoluble pesticide microencapsulated in a shell and further comprising water-soluble polymers such as acrylic acid polymers. However, the present invention relates to a microparticle wherein the active substance is not microencapsulated in a shell but is embedded into the polymer matrix (see the specification at page 2, 1st paragraph and claim 18). Moreover the microparticle of the present invention comprises a water insoluble polymer, namely a cycloolefin-copolymer. Such microparticle provides all the advantages as set forth at pages 2 and 3 of the specification. As the Examiner has correctly recognized, Lo does not disclose the use of a cycloolefin-copolymer as is required by the applicants' claimed invention. Lo describes the polymers at col. 3, lines 45-54.

Hasslin does not give a hint to modify the embodiment of Lo in the sense of the present invention in order to render the advantageous microparticle of the present invention. Hasslin discloses many different types of polymers including cycloolefin polymers (col. 3, line 35), but this disclosure is in a laundry list of polymers that extends from col. 3, line 30 through col. 5, line 64. This list includes a group of twenty-two broad groups. It is noted that none of the specific examples of commercially available polymers disclosed at col. 5, lines 51-64 include a cycloolefin copolymer. There would be no reason for a person of ordinary skill in the art to select a cycloolefin copolymer from the multitude of polymers listed. Hasslin does not even disclose the particular advantages of the cycloolefin copolymers.

With respect to the rejection over Masters and Eppel, the Examiner correctly states that Masters does not teach the claimed copolymer, such as cycloolefin. Furthermore, Master at col. 9, lines 57-60 states

"...the biodegradable polymeric material comprises a biodegradable protein. More preferably, the biodegradable polymeric material comprises a water-adsorbing, biodegradable protein. The utilization of a water-adsorbing biodegradable protein

provides the advantage that, not only will the resulting drug delivery device be biodegradable, but also resorbable.”

Master does not suggest that the biodegradable protein can be replaced, let alone with a cycloolefin copolymer.

Eppele teaches to use a mixture of at least one cycloolefin polymer and at least one polyaryl ether ketone. Eppele does not teach the functional equivalent of a cycloolefin polymer and a biodegradable protein.

The Examiner must consider the references as a whole, In re Yates, 211 USPQ 1149 (CCPA 1981). The Examiner cannot selectively pick and choose from the disclosed multitude of parameters without any direction as to the particular one selection of the reference without proper motivation. The mere fact that the prior art may be modified to reflect features of the claimed invention does not make modification, and hence claimed invention, obvious unless desirability of such modification is suggested by the prior art (In re Baird, 29 USPQ 2d 1550 (CAFC 1994) and In re Fritch, 23 USPQ 2d. 1780 (Fed. Cir. 1992)). The applicants disagree with the Examiner why one skilled in the art with the knowledge of the references would selectively modify the references in order to arrive at the applicants' claimed invention. The Examiner's argument is clearly based on hindsight reconstruction.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching, suggestion, or incentive supporting this combination, although it may have been obvious to try various combinations of teachings of the prior art references to achieve the applicant's claimed invention, such evidence does not establish prima facie case of obviousness (In re Geiger, 2 USPQ 2d. 1276 (Fed. Cir. 1987)). There would be no reason for one skilled in the art to combine

(1) Lo and Hasslin, and

(2) Masters and Eppel.

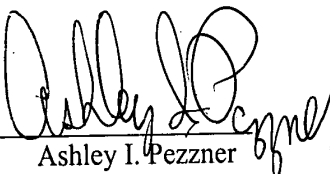
For the above reasons, these rejections should be withdrawn.

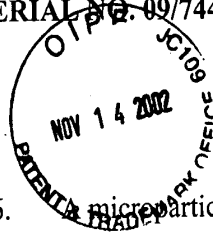
A three-month extension fee has been paid. No additional fees are due. If there are any additional fees due in connection with the filing of this response, including any fees required for an additional extension of time under 37 CFR 1.136, such an extension is requested and the Commissioner is authorized to charge or credit any overpayment to Deposit Account No. 03-2775.

For the reasons set forth above, Applicants believe that the claims are patentable over the references cited and applied by the Examiner and a prompt and favorable action is solicited. The applicants believe that these claims are in condition for allowance, however, if the Examiner disagrees, the applicants respectfully request that the Examiner telephone the undersigned at (302) 888-6270.

Respectfully submitted,

CONNOLLY BOVE LODGE & HUTZ LLP

By   
Ashley I. Pezzner  
Registration No. 35,646  
Telephone: 302/658-9141



**APPENDIX 1**  
**MARKED-UP COPY OF AMENDED CLAIMS**

16. microparticle for controlled active-substance release comprising at least one active substance and at least one cycloolefin copolymer[, which releases the active substance in a dose advantageous for the biological organism, after a particular time and/or period, allowing for some random variation depending on the circumstances].
20. The microparticle as claimed in claim 16, which further comprises at least one formulation auxiliary [or other auxiliary].
26. The microparticle as claimed in claim [18] 19, wherein the microparticle has an average diameter of from 100 to 600  $\mu\text{m}$ .